REMARKS

Applicant amended claims 1, 4, 19, 24, 26, 29, 39, 42, 44, 47, 57, 60, 62, 65, 76, 79, 81, 84, 95, 98, 100, 103, 114, and 117, and added new claims 153-194 to further define Applicant's claimed invention. New claims 153, 154, 160, 161, 167, 168, 174, 175, 181, 182, 188, and 189 are supported at least in the specification on page 10, line 5. New claims 155, 162, 169, 176, 183, and 190 are supported at least in the specification on page 17, line 9. New claims 156-158, 163-165, 170-172, 177-179, 184-186, and 191-193 are supported at least in the specification on page 15, lines 5-16. New claims 159, 166, 173, 180, 187, and 194 are supported at least in the specification on page 18, line 5.

In the Office Action, the Examiner rejected claims 1-14, 17-34, 37-52, 55-71, 74-91, 94-109, and 112-152 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,432,106 to Fraser in view of U.S. Patent No. 6,214,005 to Benzel et al.

Applicant amended the language of independent claims 1, 26, 44, 62, 81, and 100 to recite an implant adapted for use with bone screws, the implant having a trailing end with a "maximum height" as measured "along the longitudinal axis of the human spine" that is "adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space." No such structure is taught, disclosed, or suggested by Fraser and Benzel et al. either alone or when properly combined.

In Figs. 1-3 and 8, Fraser discloses a fusion cage with a plate having tabs 36', 38', 40', and 42' into which bone screws are placed through. (See, Fraser, Abstract and Col. 3, lines 7-17; Fig. 2). The trailing end of the Fraser implant has a height measured along the longitudinal axis of the human spine that is greater than the distance between the adjacent vertebral bodies. The trailing end of the Fraser implant shown in Figs. 1-3

and 8 is not adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space. In Figs. 4-6 and 9, Fraser discloses a fusion cage that is not adapted to receive bone screws.

Benzel et al. discloses a spinal column retaining apparatus including a pair of rods (12, 14) and plates (30, 32) which engage the rods along vertical axis A of the human body. Each rod has a length "which is sufficient to enable the rods to span at least the two vertebrae V1 and V2." (Benzel et al., col. 2, lines 26-35, 54, and 55 and Fig. 1). Plates 30, 32 have inner side surfaces (64, 164) adapted to engage the anterior surface of the vertebrae. (Benzel et al., Col. 3, lines 1-5; and Col. 6, lines 6-11). The plates of Benzel et al. do not have a maximum height as measured along the longitudinal axis of the spine that is adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space as recited in Applicant's claimed invention.

Applicant respectfully disagrees with the Examiner's contention that it would have been obvious to combine the teachings of Fraser and Benzel et al. to arrive at Applicant's claimed invention. Neither Fraser nor Benzel et al., whether alone or in proper combination teach, disclose, or suggest an implant adapted to receive bone screws having a trailing end with a maximum height as measured along the longitudinal axis of the human spine that is adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space.

Applicant respectfully submits that the motivation used to support the combination of Fraser with Benzel et al. is improper. The Examiner states in the Office Action that "given the teaching of Benzel et al. it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the partially circumferentially screw holes in the device Fraser to block movement of the

implant, and thereby its associated vertebral portions." (See, Office Action, page 3, second full paragraph). Applicant respectfully submits that the Examiner's asserted motivation is inapplicable because Fraser already accomplishes without modification what the Examiner states is the reason to combine the teachings of Benzel et al. with Fraser, i.e., blocking the movement of the implant relative to the associated vertebral portions. (See, e.g., Fraser, Figs. 3 and 8, bone screws 46, 48). The passage of Benzel et al. referred to by the Examiner at page 5 of the Office Action relates to the interaction of set screws with the rods, which is not applicable to the teachings of Fraser, which discloses a non-expandable fusion cage. Further, the interaction of set screws with rods has little influence on the configuration of the fastener openings as shown in Fig. 10 of Benzel et al. Thus, Applicant respectfully submits that the rejection must be withdrawn.

With respect to independent claim 44, Applicant respectfully disagrees with the Examiner's contention that Fig. 8 of Fraser shows the trailing end being adapted to receive at least a portion of a bone screw passing therein that extends beyond the maximum height of the implant immediately adjacent thereto. Fig. 8 is a side view of the embodiment of the implant of Fig. 1. (See, col. 2, lines 10 and 11). The implant of Fig. 1 includes tabs 36', 38', 40', and 42' each forming a perimeter around bone screw holes 36, 38, 40, and 42, respectively, sized to prevent at least a portion of a bone screw inserted therein from extending beyond the maximum height of the trailing end of the implant immediately adjacent thereto. (See, e.g., Fig. 2). The structure of the implant of claim 44 is not taught or disclosed by Fraser.

Applicant further submits that Fraser and Benzel et al., whether alone or in proper combination, fail to teach or suggest the subject matter of Applicant's dependent

claims. For example only, dependent claims 12, 33, 51, 70, 90, and 108 recite a pair of screw receiving holes along an upper edge and a pair of screw receiving holes along a lower edge of the trailing end of the implant, "one of said pair of bone screw receiving holes being adapted to position bone screws in a convergent relationship to one another." Neither Fraser nor Benzel et al., alone or in proper combination, teach or suggest such an arrangement.

The Examiner also rejected claims 15, 16, 35, 36, 53, 54, 72, 73, 92, 93, 110, and 111 under 35 U.S.C. § 103(a) over Fraser and Benzel et al., further in view of U.S. Patent No. 5,364,399 to Lowery et al. Applicant submits that the rejection over claims 15, 16, 35, 36, 53, 54, 72, 73, 92, 93, 110, and 111 is rendered moot at least in view of the patentability of independent claims 1, 26, 44, 62, 81, and 100, which Applicant submits are in condition for allowance and from which the rejected dependent claims depend either directly or indirectly.

Applicant submits independent claims 1, 26, 44, 62, 81, and 100 are allowable and that dependent claims 2-25, 27-43, 45-61, 63-80, 82-99, and 101-152 dependent from one of independent claims 1, 26, 44, 62, 81, and 100, or claims dependent therefrom, respectively, are allowable at least due to their dependency from an allowable independent claim. Applicant submits that the rejections of claims 1-152 over the art of record have been overcome. Applicant also submits that new claims 153-194 are allowable over art of record at least due to their dependency from an allowable independent claim.

In view of the foregoing amendments and remarks, Applicant respectfully submits that the claims are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the amendments to the claims and

preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

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CHANGES TO THE CLAIMS

1. (Twice amended) A spinal implant for insertion at least in part across at least the height of a disc space between adjacent vertebral bodies of a human spine, said implant comprising:

opposed upper and lower surfaces adapted to be placed toward and in contact with each of the adjacent vertebral bodies, respectively, from within the disc space;

a leading end for insertion into the disc space and between the adjacent vertebral bodies;

a trailing end opposite said leading end, said trailing end having an exterior surface and an outer perimeter with an upper edge and a lower edge adapted to be oriented toward the adjacent vertebral bodies, respectively, said trailing end having a maximum height as measured from said upper edge to said lower edge along the longitudinal axis of the human spine, said maximum height being adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space; and

a plurality of bone screw receiving holes in said trailing end, at least one of which is adapted to only partially circumferentially surround a trailing end of a bone screw adapted to be received therein, at least one of said bone screw receiving holes passing through said exterior surface and one of said edges so as to permit the trailing end of the bone screw to protrude beyond said one of said edges.

4. (Twice amended) The implant of claim 1, wherein said implant has a height equal to the distance between the adjacent vertebral bodies of a surgically corrected~~normal~~ disc space.

19. (Amended) The implant of claim 18, wherein said bone growth promoting material is ~~selected from~~at least one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

24. (Amended) The implant of claim 23, wherein said bone growth promoting material is ~~selected from~~at least one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

26. (Twice amended) A spinal implant for insertion at least in part across at least the height of a disc space between adjacent vertebral bodies of a human spine, said implant comprising:

opposed upper and lower surfaces adapted to be placed toward and in contact with one each of the adjacent vertebral bodies, respectively, from within the disc space;

a leading end for insertion between the adjacent vertebral bodies; and

a trailing end opposite said leading end, said trailing end having an upper edge and a lower edge, said trailing end having a maximum height as measured from said upper edge to said lower edge along the longitudinal axis of the human spine, said maximum height being adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space, said trailing end being adapted to only partially circumferentially surround the circumference of at least one bone screw adapted to be received therein.

29. (Twice amended) The implant of claim 26, wherein said implant has a height equal to the distance between the adjacent vertebral bodies of a surgically corrected~~normal~~ disc space.

39. (Amended) The implant of claim 38, wherein said bone growth promoting

material is ~~selected from~~at least one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

42. (Amended) The implant of claim 41, wherein said bone growth promoting material is ~~selected from~~at least one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

44. (Twice amended) A spinal implant for insertion at least in part across at least the height of a disc space between adjacent vertebral bodies of a human spine, said implant comprising:

opposed upper and lower portions adapted to be placed toward and in contact with each one of the adjacent vertebral bodies, respectively, from within the disc space;

a leading end for insertion into the disc space and between the adjacent vertebral bodies; and

a trailing end opposite said leading end, said trailing end having an upper edge, a lower edge, and a maximum height ~~therebetween~~ as measured from said upper edge to said lower edge along the longitudinal axis of the human spine, said maximum height being adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space, said trailing end being adapted to receive at least a portion of a bone screw passing therein that extends beyond said maximum height immediately adjacent thereto.

47. (Twice amended) The implant of claim 44, wherein said implant has a height equal to the distance between the adjacent vertebral bodies of a surgically corrected~~normal~~ disc space.

57. (Amended) The implant of claim 56, wherein said bone growth promoting

material is ~~selected from~~at least one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

60. (Amended) The implant of claim 59, wherein said bone growth promoting material is ~~selected from~~at least one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

62. (Twice amended) A spinal implant for insertion at least in part across at least the height of a disc space between adjacent vertebral bodies of a human spine, said implant comprising:

opposed upper and lower surfaces adapted to be placed toward and in contact with each one of the adjacent vertebral bodies, respectively, from within the disc space;

a leading end for insertion into the disc space and between the adjacent vertebral bodies; and

a trailing end opposite said leading end, said trailing end having a plurality of bone screw receiving holes, an upper edge, a lower edge, and a maximum height ~~therebetween~~ as measured from said upper edge to said lower edge along the longitudinal axis of the human spine, said maximum height being adapted to fit into the disc space and between the vertebral bodies adjacent to the disc space, said maximum height of said trailing end being adapted to be less than the sum of the maximum diameter of two bone screws adapted to be inserted in said bone screw receiving holes, said bone screw receiving holes being adapted to incompletely circumferentially receive at least one of the bone screws.

65. (Twice amended) The implant of claim 62, wherein said implant has a height equal to the distance between the adjacent vertebral bodies of a surgically

correctednormal disc space.

76. (Amended) The implant of claim 75, wherein said bone growth promoting material is selected fromat least one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

79. (Amended) The implant of claim 62, wherein said bone growth promoting material is selected fromat least one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

81. (Twice amended) A spinal fusion implant for insertion at least in part across at least the height of a disc space between adjacent vertebral bodies of a human spine, said implant comprising:

opposed upper and lower surfaces adapted to be placed toward and in contact with each of the opposed adjacent vertebral bodies, respectively, from within the disc space;

a leading end for insertion into the disc space and between the adjacent vertebral bodies;

a trailing end opposite said leading end, said trailing end having an exterior surface and an outer perimeter with an upper edge and a lower edge adapted to be oriented toward the adjacent vertebral bodies, respectively, said trailing end having a maximum height as measured from said upper edge to said lower edge along the longitudinal axis of the human spine, said maximum height being adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space; and

a plurality of bone screw receiving holes in said trailing end, at least one of which is adapted to only partially circumferentially surround the trailing end of a bone screw

adapted to be received therein, at least one of said screw receiving holes passing through said exterior surface and one of said edges so as to permit the bone screw to protrude over one of said edges within a plane of said trailing end; and

at least one bone screw, said screw having:

a leading end for placement in the vertebral body; and opposite,

a trailing end adapted to cooperatively engage said implant so as to prevent the further advancement of the screw into the bone and to be retained within said implant.

84. (Twice amended) The implant of claim 81, wherein said implant has a height equal to the distance between the adjacent vertebral bodies of a surgically correctednormal disc space.

95. (Amended) The implant of claim 94, wherein said bone growth promoting material is selected fromat least one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

98. (Amended) The implant of claim 97, wherein said bone growth promoting material is selected fromat least one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

100. (Twice amended) An interbody spinal implant for insertion at least in part across at least the height of a disc space between adjacent vertebral bodies of a human spine, said implant comprising:

opposed upper and lower surfaces adapted to be placed toward and in contact with each of the adjacent vertebral bodies, respectively, from within the disc space;

a leading end for insertion into the disc space between the adjacent vertebral bodies; and

a trailing end opposite said leading end, said trailing end having an exterior surface and an outer perimeter with an upper edge and a lower edge adapted to be oriented toward the adjacent vertebral bodies, respectively, said trailing end having a maximum height as measured from said upper edge to said lower edge along the longitudinal axis of the human spine, said maximum height being adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space; said outer perimeter having at least one gap therein for permitting a portion of a bone screw to protrude over the outer perimeter of said trailing end within a plane of said trailing end, said gap being sufficient to retain a trailing end of the bone screw.

103. (Twice amended) The implant of claim 100, wherein said implant has a height equal to the distance between the adjacent vertebral bodies of a surgically correctednormal disc space.

114. (Amended) The implant of claim 113, wherein said bone growth promoting material is selected fromat least one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

117. (Amended) The implant of claim 116, wherein said bone growth promoting material is selected fromat least one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.